

REMARKS

Claim Rejections

Claims 1, 2, 17 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Feijen (5,041,292). Claims 1-24 stand rejected under 35 U.S.C. §103(a) as being rendered obvious by Silver et al. (4,970,298) taken in view of the aforementioned patent to Feijen and Silver et al. (4,703,108). Claims 1-24 stand further rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

In addition, the Examiner has objected to the specification under 35 U.S.C. § 112, first paragraph and has required Applicant to submit a Substitute Specification.

Substitute Specification

Applicant is submitting herewith a Substitute Specification as required by the Examiner. Accompanying the Substitute Specification is a marked-up copy of the original specification indicating the changes made thereto by the Substitute Specification. No "new matter" has been added to the original disclosure by the Substitute Specification. Entry of the Substitute Specification is respectfully requested.

New Claims

By this Amendment, Applicant has canceled claims 1-24 and has added new claims 25-47 to this application. It is believed that the new claims specifically set forth each element of Applicant's invention in full compliance with 35 U.S.C. § 112, thereby overcoming the rejection of original claims 1-24 under 35 U.S.C. § 112, second paragraph. It is also believed that the new claims define subject matter that is patentably distinguishable over the cited prior art, taken individually or in combination.

The new claims define a method for producing cross-lined polysaccharide-protein bio-composites, comprising the steps of: a) preparing a mixture of polysaccharide solution and a protein solution at a weight ratio of polysaccharide to

protein in a range of 20/80 to 80/20; b) adjusting the mixture at a pH value between 3 and 11 by adding either an acid or a hydroxide, degassing, forming into a desired shape, and lyophilizing to give a matrix having a desired shape; and c) subjecting the matrix to cross-linking reaction by using a cross-linking agent in a mixture of water and organic solvents.

Claims 26-47 all directly or indirectly depend from Applicant's new claim 25 and further define various characteristics of Applicant's method.

It is not believed that any of the cited references, taken individually, disclose the method now set forth in Applicant's new claims. The reference to Feijen (5,041,292) discloses a method for making micro-spheres useful in the control and release of drugs other than producing a matrix used as an artificial skin to enhance the healing of a wound. Unlike Applicant's invention, the method disclosed in Feijen requires an emulsification step using an emulsifier, since it uses oils which are water immiscible. Thus, Applicant submits that Feijen does not disclose each and every feature of Applicant's new claims and, therefore, could not possibly anticipate any of Applicant's new claims under 35 U.S.C. § 102.

A reference to Silver et al. (4,970,298) discloses a method for the preparation of a collagen-based sponge, in which the disclosed method is conducted in water without any organic solvent. Accordingly, a cross-linked cluster matrix could not be subjected to further cross-linking reaction and the prepared matrix is not homogeneous. In the examples set forth in Silver et al. ('298), no organic solvent is included in the preparation of the collagen-based sponge. Silver et al. ('298) is directed toward the concept of producing a sponge matrix, in contrast to Applicant's method which produces a bio-compatible matrix in various shapes as desired.

The secondary reference to Silver et al. (4,703,108) discloses a method for preparing a biodegradable collagen-based matrix in sponge or sheet form which includes two cross-linking steps. Applicant submits that the specific steps set forth in Silver et al. ('108) are different from those now set forth in Applicant's claimed method.

It is a basic principle of patent law that it is improper to arbitrarily pick and choose prior art patents and combine selected portions of the selected patents on the basis of Applicant's disclosure to create a hypothetical combination which

allegedly renders a claim obvious, unless there is some direction in the selected prior art patents to combine the selected teachings in a manner to negate the patentability of the claimed subject matter. This principle was enunciated over 30 years ago by the Court of Customs and Patent Appeals in In re Rothermel and Waddell, 125 USPQ 328 (CCPA 1960) wherein the court stated, at page 331:

The examiner and the board in rejecting the appealed claims did so by what appears to us to be a piecemeal reconstruction of the prior art patents in the light of appellants' disclosure. ...

It is easy now to attribute to this prior art the knowledge which was first made available by appellants and then to assume that it would have been obvious to one having the ordinary skill in the art to make these suggested reconstructions. While such a reconstruction of the art may be an alluring way to rationalize a rejection of the claims, it is not the type of rejection which the statute authorizes.

The same determination was made by the Court of Appeals for the Federal Circuit in ACS Hospital Systems Inc. v. Montefiore Hospital, 221 USPQ 929 (Fed.Cir. 1984) wherein the court stated, at page 933:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under § 103, teachings of references can be combined only if there is some suggestion or incentive to do so. The prior art of record fails to provide any such suggestion or incentive. Accordingly, we hold that the court below erred as a matter of law in concluding that the claimed invention would have been obvious to one of ordinary skill in the art under § 103.

It is believed to be well established that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Applicant submits that none of the references cited by the Examiner contains the slightest

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suggestion that it's teachings may be combined with the others in the manner suggested by the Examiner. Applicant respectfully traverses the outstanding rejection of Applicant's claims under 35 U.S.C. § 103.

Summary

In view of the foregoing, Applicant submits that this application is now in condition for allowance and such action is respectfully requested. Should any points remain in issue, which the Examiner feels could best be resolved by either a personal or a telephone interview, it is urged that Applicant's local attorney be contacted at the exchange listed below.

Respectfully submitted,

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By:



Bruce H. Troxell
Reg. No. 26,592

TROXELL LAW OFFICE PLLC
5205 Leesburg Pike, Suite 1404
Falls Church, Virginia 22041
Telephone: 703 575-2711
Telefax: 703 575-2707